

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

SEPRACOR INC., et al.,

Plaintiffs,

v.

SUN PHARMACEUTICAL INDUSTRIES
LTD., et al.,

Defendants.

Civil Action No. 07-CV-4213 (MLC)

RECEIVED

DEC 17 2008

AT 8:30
WILLIAM T. WALSH
CLERK

STIPULATION AND ORDER

The Court, upon the consent and request of Plaintiffs Sepracor Inc. and University of Massachusetts (collectively, "Sepracor") and Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, "Lupin"), hereby acknowledges the following Stipulation and issues the following Order.

STIPULATION

1. This Court has subject matter jurisdiction over this patent infringement action (the "Action") and personal jurisdiction over Sepracor and Lupin. Venue is proper in this Court as to Sepracor and Lupin.

2. In this Action, Sepracor has charged Lupin with infringement of United States Patent Nos. 7,214,683 ("the '683 patent") and 7,214,684 ("the '684 patent") in connection with Lupin's submission of Abbreviated New Drug Application ("ANDA") No. 78-352 directed to generic tablets containing 5 milligrams of desloratadine per tablet to the U.S. Food and Drug Administration ("FDA").

3. In response to Sepracor's charges of patent infringement, Lupin has alleged certain defenses, including that the '683 patent and the '684 patent are invalid and not

infringed by the generic tablet product containing 5 milligrams of desloratadine per tablet that is the subject of ANDA No. 78-352. No decision has been obtained by either party from this Court regarding these charges of infringement or these defenses.

4. Lupin has not rebutted the statutory presumption that the '683 patent and the '684 patent are valid and enforceable in this Action. This admission is without prejudice to Lupin's defenses and counterclaims that the '683 patent and the '684 patent are invalid.

5. Lupin admits that the submission of ANDA No. 78-352 to FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use and/or sale of generic tablets containing 5 milligrams of desloratadine per tablet within the United States before the expiration of the '683 patent and the '684 patent was a technical act of infringement of those patents under 35 U.S.C. § 271(e)(2)(A). This admission is without prejudice to Lupin's defenses and counterclaims that the '683 patent and the '684 patent are invalid and/or that the product described by ANDA No. 78-352 does not infringe either patent.

6. Lupin has agreed that each of the defenses set forth in Lupin's Answer, Defenses and Counterclaims, including the allegations and averments contained therein, should be dismissed, without prejudice.

7. Sepracor and Lupin make the following releases: (a) Lupin hereby releases and discharges Sepracor and its respective Affiliates, successors, assigns, directors, officers, employees, agents and customers from all causes of action, demands, claims, damages and liabilities of any nature, whether known or unknown, arising from or in connection with this Action, or the '683 Patent and/or the '684 Patent, including, without limitation, all claims that Lupin has asserted or could have asserted in this Action; (b) Sepracor hereby releases and discharges Lupin and its Affiliates, successors, assigns, directors, officers, employees, agents and

customers from all causes of action, demands, claims, damages and liabilities of any nature, whether known or unknown, arising from or in connection with this Action, or the '683 Patent and/or '684 Patent, including, without limitation, all claims that Sepracor has asserted or could have asserted in this Action; and (c) neither Sepracor or Lupin, nor any of their Affiliates or agents shall institute any new litigation with respect to the '683 Patent, the '684 Patent, U.S. Patent Nos. 7,211,582; 5,731,319; and 5,595,997, and any other patents owned by Sepracor or its Affiliates that would be infringed by the manufacture, having manufactured, and/or marketing of any Generic Desloratadine Product, including any continuations, continuations-in-part, divisionals, reissues or reexaminations thereof (collectively the "Desloratadine Patents ") against any product covered by ANDA No. 78-352 or any Lupin ANDA covering any plain (*i.e.*, not rapidly dissolving) tablet product that contains desloratadine as the sole active ingredient and that is approved for marketing in the United States of America (collectively the "Generic Desloratadine Products"). Notwithstanding any of the above, nothing in this Stipulation shall prevent Sepracor or Lupin from instituting litigation against the other party involving a product other than a Generic Desloratadine Product, in which event nothing in this Stipulation shall prevent: (a) Sepracor from asserting in such litigation that such other product or products infringe any of the Desloratadine Patents or other patents, or (b) Lupin from asserting in such litigation that any of the Desloratadine Patents or other patents are not infringed, invalid and unenforceable.

ORDER

Accordingly, pursuant to the above Stipulation, and upon the consent and request of Sepracor and Lupin, **IT IS HEREBY ORDERED, ADJUDGED AND DECREED THAT:**

1. The filing of ANDA No. 78-352 was a technical act of infringement of the '683 patent and the '684 patent under 35 U.S.C. § 271(e)(2)(A). No decision of the Court has been obtained by either party regarding the presumptive validity of the '683 patent and the '684 patent and/or whether the product described by ANDA No. 78-352 infringes either patent.

2. Lupin's defenses with respect to the '683 patent and the '684 patent are hereby dismissed, without prejudice.

3. Lupin, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, the generic tablet product containing 5 milligrams of desloratadine per tablet that is the subject of ANDA No. 78-352 during the life of the '683 patent and the '684 patent, including any extensions and pediatric exclusivities, except pursuant to a license and/or sublicense agreement, as applicable, or other authorization by Sepracor, unless all of the claims of the '683 patent and the '684 patent are found invalid or unenforceable by a court decision from which no appeal has been or can be taken, other than a petition for a writ of certiorari to the U.S. Supreme Court.

4. Sepracor and Lupin each expressly waives any right to appeal or otherwise move for relief from this Stipulation And Order.

5. This Court retains jurisdiction over Sepracor and Lupin for purposes of enforcing this Stipulation And Order.

6. This Stipulation And Order shall finally resolve this Action between Sepracor and Lupin. Each party shall bear its own fees and costs in connection with this Action, including attorney fees.

7. The Clerk of the Court is directed to enter this Stipulation And Order forthwith.

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UNIVERSITY OF MASSACHUSETTS



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SO ORDERED:

This 17th day of DEC., 2008


HONORABLE MARY L. COOPER
UNITED STATES DISTRICT JUDGE